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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,474	11/13/2003	Ihab M. Hekal	62357.017508	3231
45599	7590	02/04/2005	EXAMINER	
GREENBERG TRAURIG LLP			MCDOWELL, SUZANNE E	
MET LIFE BUILDING			ART UNIT	
200 PARK AVENUE			PAPER NUMBER	
NEW YORK, NY 10166			1732	

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/714,474

Applicant(s)

HEKAL, IHAB M.

Examiner

Suzanne E. McDowell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-36 is/are allowed.
- 6) ☐ Claim(s) 37-42, 46-54 and 58-60 is/are rejected.
- 7) ☒ Claim(s) 43-45 and 55-57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Reissue Applications***

1. Claims 37-42, 46-54 and 58-60 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows:

In claims 37-42, 46-54 and 58-60, the agent is not claimed as being hydrophilic. The specification only teaches a hydrophilic agent.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 37-42, 46-54 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hydrophilic agent, does not reasonably provide enablement for an agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification teaches that the agent is hydrophilic; see column 2, lines 35-41; column 4, lines 4-10; column 12, lines 62-67.

### ***Allowable Subject Matter***

4. Claims 1-36 are allowed.
5. Claims 43-45 and 55-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. The following is a statement of reasons for the allowance of claims 1-36 and for the indication of allowable subject matter: the prior art does not teach or fairly suggest, in an article of manufacture comprising a monolithic composition of a water-insoluble polymer, a hydrophilic agent, and a releasing

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material, the limitation that the affinity between the agent and the releasing material is great than between the polymer and the releasing material and the composition comprises an interconnecting channel composed of the agent. Claims 43-45 and 55-57 are allowable because the specific solubility language of the original claims in US Patent 6,316,520 did not determine patentability of the original claims.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne E. McDowell whose telephone number is (571) 272-1205. The examiner can normally be reached on M, W, Th 6:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEM  
October 1, 2004

  
SUZANNE E. MCDOWELL  
PRIMARY EXAMINER